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(54) **Multi-motion multiple biopsy sampling device**

(57) An instrument (10) is provided for obtaining multiple tissue samples (40) from sites within a body (18) without being withdrawn from the body (18), the instrument (10) comprises an elongated body (24) having a distal end (16), a storage space (27) defined by the elongated body (24) along the axis of the elongated body (24) near the distal end (16), the storage space (27) being suitable for storage of multiple samples (40), a sampling assembly (20, 21) having a first cutting mem-

ber (20) and a second cutting member (21), the sampling assembly (20, 21) is joined to the elongate body (24) proximate the distal end (16) of the elongated body (24) and being actuatable in a first, radial opening and closing motion to take a tissue sample (40) from the body (18) and a second, axial motion wherein at least one of the first and second cutting members (20, 21) is movable relative to the elongated body (24) so as to pull the sample into the storage space (27).

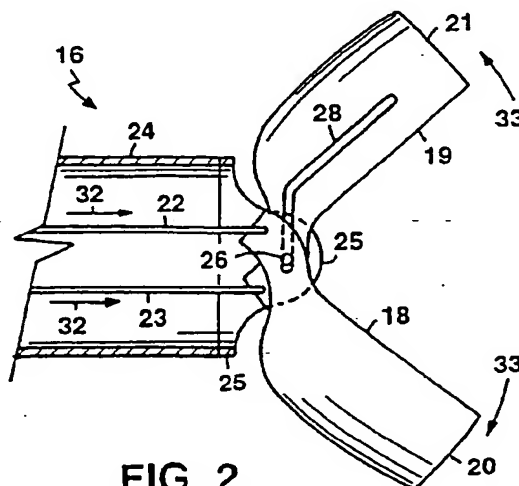


FIG. 2

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Description

Field of the Invention

[0001] This invention relates to taking samples of tissue from the body.

Background of the Invention

[0002] Tissue samples can be examined in a laboratory to determine the presence of a pathological disorder (e.g. malignancy). Often, the samples must be obtained from deep within the body using a medical sampling instrument. It is usually best to obtain several samples around the location where the disorder is suspected so that the presence and progress of disease, if any, can be accurately determined. The samples must be catalogued according to the location from which each sample is taken and the integrity of the samples must be maintained for the subsequent laboratory analysis.

Summary of the Invention

[0003] According to the present invention there is provided an instrument for obtaining multiple tissue samples from sites within a body without being withdrawn from the body, the instrument comprising:

an elongated body having a distal end;
a storage space defined by the elongated body along the axis of the elongated body near the distal end, the storage space suitable for storage of multiple samples;
a sampling assembly having a first cutting member and a second cutting member, the sampling assembly joined to the elongate body proximate the distal end of the elongated body and being actuatable in a first, radial opening and closing motion to take a tissue sample from the body and a second, axial motion wherein at least one of the first and second cutting members is movable relative to the elongated body so as to pull the sample into the storage space.

[0004] The sampling assembly may be a jaw-like cutting member having a first jaw and a second jaw.

[0005] The first cutting member may be radially movable and axially stationary, and the second cutting member may be radially and axially movable.

[0006] The second cutting member may be configured to move transversely into space defined by the first cutting member to engage and dispose the sample into the storage space.

[0007] Both the first and second cutting members may be radially and axially movable.

[0008] The sampling assembly may be configured to return to a sample cutting position with the sample disposed in the storage space for preparation of taking an-

other sample without being withdrawn from the body.

[0009] The second, axial motion may be limited between a sample cutting position and a position in the storage space near the distal end for disposing the sample axially into the storage space.

[0010] The sampling assembly may be joined to the elongated body via a camming arrangement, whereby the axial motion of at least one of the first and second cutting members relative to the elongated body causes the radial and axial motions of the first and second cutting members.

[0011] The camming arrangement may include a slot and a pin, wherein one of the slot and the pin is provided on the sampling assembly and the other of the slot and the pin is provided on the elongated body.

[0012] The instrument may further comprise another set of camming arrangement including a second slot on the sample assembly and a third slot on the elongated body, the second and third slots configured to engage each other for disposing the sample into the storage space.

[0013] The camming arrangement may provide opening and closing motions of the first and second cutting members for cutting the sample, axial motion of the at least one of the first and second cutting members for engaging and disposing the sample in the storage space, and axial motion of at least one of the first and second cutting members for returning the sampling assembly to the sample cutting position.

[0014] The sampling assembly may be coupled to a distal end portion of the elongated body, the distal end portion being rigid relative to the flexible portion of the elongated body.

[0015] The rigid distal end portion may have an axial length that is approximately equal to or shorter than the axial length of the sampling assembly.

[0016] The rigid distal end portion may define a space that has an axial length that is approximately equal to the axial length of the sampling assembly and the sampling assembly is moveable proximally within the distal end portion.

[0017] The distal end portion may have a length of about 5-7 mm.

[0018] The instrument may have a diameter sized to pass through an endoscope.

[0019] The instrument may have a length in the range of about 100.-250 cm.

[0020] The cutting member may be attached to a tubular member defining the storage space. The tubular member and cutting member may include a slot and pin camming arrangement constructed to allow the motions by relative axial movement of the tubular member and the cutting member. The slot is provided on the cutting member and the pin is provided on the tubular member. The camming arrangement may provide, in order, opening motion of the cutting member, closing motion of the cutting member, transverse motion of the cutting member to facilitate engagement with a sample cut by the

member, axial motion for disposing the sample in the storage space, and axial motion for returning the cutting member to a position in preparation for taking another sample.

[0021] Other features and advantages and methods of use follow.

Brief Description of the Drawings

[0022] We first briefly describe the drawings.

Fig. 1 is a perspective view of an embodiment of the invention being delivered into the body through an endoscope;

Fig. 2 is a cross-sectional view of an embodiment with the jaws open,

Fig. 2a is an end-on cross-sectional view of the embodiment with the jaws open, and Fig. 2b is a perspective view of one of the jaws;

Fig. 3 is a cross-sectional view of an embodiment of the invention with the jaws closed;

Fig. 4 is a cross-sectional side view with one of the jaws retracted;

Figs. 5-5e illustrate a use of another embodiment;

Fig. 6 is a side view of another embodiment with the jaws open, while Fig. 6a is a similar view with the jaws closed, and Fig. 6b is a similar view with the jaws retracted; and

Fig. 7-7e are views of components of the embodiment of Fig. 6, including a side view of a coupling section (Fig. 7), a perspective view of the coupling section (Fig. 7a), a side view of a jaw (Fig. 7b), a top view of a jaw (Fig. 7c), a perspective view of a jaw (Fig. 7d), and a top view showing a stamped cut piece of metal that can be subsequently formed into a jaw (Fig. 7e).

Description of the Preferred Embodiments

[0023] Referring to Fig. 1, the device 10 for multiple biopsy sampling may be delivered into the body through the channel of an endoscope device 11 (e.g., gastro-scope, sigmoidoscope, or colonoscope). The endoscope device typically has a length of about 100-250 cm and a channel diameter of 2.0-3.8 mm, typically about 2.8 mm. A distal sampling portion 16 is extended from the endoscope for cutting and storing a sample of tissue from a body surface 18 of a patient (e.g. from a surface in the gastrointestinal tract or bronchial tract). The device has a diameter of preferably around 1.8 - 2.4 mm, typically about 2.3 mm or less and is of sufficient flexibility so it passes easily though the channel when the endoscope follows a tortuous body passageway. The endoscope may include other lumens for water, air, suction, and viewing, for example. Devices according to the invention can be adapted to be introduced to sites (e.g., urinary tract, reproductive organs, cardiac tissue, or the like) deep within the body by other means. For example,

a device can be configured with a lumen so that it can be advanced over a guidewire, e.g., in vascular applications. The device may be passed through an introducer or guiding catheter in, e.g., cardiac applications. The sampling and storage arrangements may be useful in open surgery applications.

[0024] Referring particularly to Figs. 2-4, the sampling portion 16 includes jaws 20, 21, coupling section 25, control wires 22, 23, and sleeve 24. All or part of surfaces 18 and 19, on jaws 20, 21, may be sharpened or serrated to facilitate cutting. Each jaw 20 and 21 also has ear-forms 29. Control wires (or rods) 22, 23 are connected to the proximal end of ear-forms 29 and are used to radially open and close jaws 20 and 21 by manipulating the control wires 22, 23 from outside the body, as will be discussed further below. On jaw 20, ear-form 29 has a bore 30 and on jaw 21 ear-form 29 has a cam slot 28. Jaws 20 and 21 are attached to sleeve 24 by rigid coupling section 25 using pivot pins 26. Pivot pins 26 are cantilevered from coupling section 25 and extend through cam slot 28 and bore 30. Sleeve 24 has storage space 27 to store at least, preferably five or more, samples.

[0025] Ear-forms 29 are constructed so they act in cooperation with pivot pins 26 such that axial force by the control wires 22, 23 is cammed to radial motion of jaws 20, 21. Cam slot 28 in jaw 21 has a width of about 0.0762mm (0.003 inch) and is formed in the side flattened portion 31 of jaw 21. Side flattened portion 31 is about 0.127mm-0.1524mm (0.005-0.006 inch) wide (Fig. 2b). The axial length of jaw 21 is about 5-7 mm. Jaw 21 is slightly shorter and narrower than jaw 20 so that jaw 21 can fit at least partially inside jaw 20, as will be discussed below. The circumferential shape of the jaws 20, 21 must be complementary to the shape of the coupling section 25 and storage space 27 so that travel along the cam slot 28 does not cause transverse motion of the jaws 20, 21.

[0026] Referring particularly to Fig. 2, with control wires 22, 23 pushed distally, the jaws are forced into an open position by radial rotation about the pivot axis defined by the pins 26 (arrows 32, 33). Referring particularly to Fig. 3, with control wires 22, 23 pulled proximally, the jaws are forced into a closed position (arrows 34, 35). Referring particularly to Fig. 4, with control wire 23 pulled further proximally, the jaw 21, following a path defined by the cam slot 28, first moves transversely into the space defined by jaw 20, to grasp or capture the sample that has been cut (not shown), and then proximally, to draw the sample into storage space 27 (arrows 36, 37). The proximal portion of jaw 21 includes a cutaway 38 (see Fig. 2a) so that jaw 21 does not bind on a sample which has been placed in storage space 27 as jaw 21 moves distally from the storage space to prepare to cut another sample.

[0027] The pivot pins 26 are cantilevered from coupling section 25 so as not to extend across the diameter of the device thus providing a relatively large storage

space 27 for storing samples. Previous samples can be stored in storage space 27 while succeeding samples are taken, thus allowing multiple samples to be taken without removing the device from the endoscope. Sleeve 24 may include lumens (not shown) for control wires 22, 23 to separate the control wires 22, 23 from samples stored inside the storage space 27 and enable the control wires 22, 23 to move freely.

[0028] In alternative embodiments, the sample storage space may include a barbed spear-form member (not shown), e.g., a stationary or axially moveable barbed spear-form, to pierce the samples and hold them in place. The axially moveable jaw 21 may include a member extending from the control portion 29, radially across the space 27. This member bears on previously taken samples to help urge them proximally as a succeeding sample is being drawn proximally into the space by jaw 21. The member can be made flexible or adjustable so that it does not push the last taken sample distally as the jaw 21 moves distally to prepare to take an additional sample. Further, a separate, axially moveable rake-type member could be provided to bear on previously taken samples to help urge them proximally as a succeeding sample is being drawn proximally into the space by jaw 21.

[0029] An advantage of this embodiment is that the distal end of the device is rigid for only a relatively short axial length, which makes it easier to thread the device through tortuous passageways with sharp curves. In the preferred embodiment, only the jaws 20, 21 and the short coupling section 25 (total length, typically 5-14 mm) are relatively rigid. These components are formed of metal or a stiff polymer such as Ultem (polyetharamide, General Electric) that can withstand the forces applied during jaw actuation. The proximal portion, such as the sleeve 24, is highly flexible. It is formed of a flexible polymer and/or surrounded by a flexible coil. The storage portion therefore, may also be flexible for most of its length. The device can be configured to take and store many samples, e.g., greater than fifteen, from a highly tortuous body passage way due to the short, stiff distal portion and long, flexible sleeve 24. In embodiments, both of the jaws can be made axially moveable. In this case, the stiff coupling section 25 may be of comparable length to jaws 20, 21 so the jaws 20, 21 can be placed inside the coupling section 25 during entry into and removal from the body.

[0030] Referring to Figs. 5a-5e, particularly Fig. 5, in use, jaws 20, 21 of the device are first brought close to a tissue surface 18 where a sample is to be taken: (In this illustration, the cam slot 28 is positioned near the top of the jaw 21 to maximize the transverse motion).

[0031] Referring to Fig. 5a, control wires 22, 23 are pushed distally to force open jaw members 20, 21 by acting against the pivot pins 26. With jaws 20, 21 open, the device is advanced so the jaws come in contact with tissue surface 18.

[0032] Referring to Fig. 5b, the control wires are

pulled proximally to close jaws 20, 21 and to separate a first sample 40 from tissue surface 18.

[0033] Referring to Figs. 5c and 5d, the first sample 40 is brought into sample storage space 27 by pulling on control wire 22, moving jaw 21 proximally with respect to jaw 20. Referring particularly to Fig. 5c, cam slot 28 is arranged so that jaw 21 moves transversely into jaw 20 to trap the sample 40. Referring particularly to Fig. 5d, continued proximal movement of control wire 22 moves jaw 21 axially to place the sample 40 in sample storage space 27. Control wire 22 is then pushed distally to return jaw 21 to a position opposing jaw 20.

[0034] Referring to Fig. 5e, subsequent samples 42-46 can be taken without removing the device from the endoscope by repeating the above sequence. The samples 42-46 are brought into the sample storage space 27 in the order in which they were collected. After sufficient samples have been taken, the device is removed from the endoscope and the samples recovered, e.g. by using a pusher (not shown) inside the sample space 27 to push the samples out through the open jaws.

[0035] Referring to Fig. 6-7a in another embodiment the sampling portion 48 includes jaws 50 that can be radially opened (Fig. 6) and closed (Fig. 6a), to take a sample, and then drawn axially proximally, to pull the sample into a storage space 56 (Fig. 6b). (When jaws 50 are in the closed position, surfaces 52 are in contact with one another. The drawings show otherwise for clarity). All or part of surface 52 of jaws 50 may be sharpened or serrated to facilitate cutting. The embodiment includes a relatively flexible proximal sleeve 54 defining most of the storage space 56 and a relatively stiff coupling section 58. The coupling section 58 includes two sets of cam slots for defining the motion of each of the jaws. Each of the sets includes a cam track 60 on the sides of the coupling section 58 and cam slot 62 that is near the top and bottom of the coupling section 58. The cam track 60 defines a track for pins 64 that are attached to ear-forms 66 extending proximally from the jaws (jaws and ear-forms integrally formed of 0.1016mm (0.004 inch) stainless steel). The cam slots 62 couple to jaw slots 68 so the top portion 51 of jaws 50 can ride on the outside of the coupling section 58 as the jaws 50 are drawn proximally into the storage space 56. (To assemble the device, the jaw slots 68 are closed (e.g. by welding) at the back portion 55 after the jaws have been aligned and positioned on the device.) The jaws 50 are controlled by control wires 70 (0.1016mm (0.004 inch) steel cable)-that are attached to the interior extensions 72 of the pins 64 (Fig. 7c) and can be extended or withdrawn from outside the body. The coupling section 58 is relatively rigid, e.g. a metal (0.1016mm (0.004 inch) thick stainless steel), and the sleeve 54 is relatively flexible, e.g. a polymer. The axial length of the coupling section is approximately the same as the jaws 50, e.g. 5-7mm.

[0036] In use, the device is inserted into the body, e.

g. through an endoscope, with the jaws retracted into the coupling section 58 (Fig. 6b). The relatively stiff coupling section 58 provides protection for the jaws 50 during delivery into and removal from the body (and thus allows the jaws to be made thinner, cheaper, and more flexible). Moreover, retracting the jaws 50 makes delivery through tortuous passageways easier since the length of the stiff portions of the device is reduced compared to the jaw extended configuration. Once the sampling site is reached, the jaws 50 can be extended out of the coupling section 58 by extending the control wires 70 which causes the pins 64 on the jaw ears-forms 66 to follow the cam track 60 to a point where the track bends (Fig. 6a). At the same time, the top portion 51 of the jaw 50 travels over the top 53 of the coupling section 58 as allowed by the cam slots 62 on the coupling section and jaw slots 68 on the top of the jaws 50. The jaws 50 are opened by continuing to extend the control wires 70, which causes the pins 64 to follow the cam track 60 in a transverse direction. The top of the jaws, having reached the proximal end of jaw slot 68 and the distal end of cam slot 62, pivot about the location where the proximal end of the jaw slot 68 engages the distal end of slot 62 (Fig. 6). The open jaws 50 are pushed forward against the tissue surface 80 where a sample is to be taken (not shown). The jaws 50 are then closed by withdrawing the control wires 70, causing the pins 64 to travel transversely and the jaws 50 to pivot closed about the distal end of the slot 62. With the jaws 50 closed, the sample, now cut and captured between the jaws 50 (not shown), can be pulled proximally by further withdrawing the control wires 70 so the pins 64 follow the axial portion of the cam track 60 and the top portion 51 of the jaws 50 slides over the top portion 53 of the coupling section 58. The sequence above can be repeated to take additional samples without removing the device from the body. Each successive sample is drawn back by the jaws 50, pushing the previous samples proximally into the storage space 56 within sleeve 54. When a sufficient number of samples have been taken, the jaws 50 are retracted into the coupling section 58 to protect them and reduce the axial stiffness, and the device is removed from the body. The samples can be retrieved by opening the jaws and providing gentle suction to draw them from the distal end. Alternatively, a pusher, which can be extended distally from the proximal end of the storage space can be used to push the samples out of the open jaws.

[0037] As shown in Fig. 7e, the jaw 50 may be made from flat stock that is stamped, cut out, and then formed into the three dimensional jaw by welding, for example.

[0038] In embodiments, optionally, the device can be provided with alternate means to facilitate drawing samples into the storage space, such as an axially moveable barbed spear-form that can be extended to pierce the samples and then drawn proximally. A tongue or rake-shaped member can also be provided for this purpose. The jaws can also be moved separately. For example,

one jaw can be moved relative to the other jaw to create a shearing action that helps cut tissue from a surface after it has been grasped by the jaws. This reduces the amount of force needed in radial motion to perform the cutting function and thus allows thinner, more flexible jaw construction. Preferably, the jaws are provided with serrated cutting edges when used in this way.

[0039] Still other embodiments are within the following claims. For example, the radial and axial motion of the jaw could be provided by multiple control wires attached directly to the jaw. One wire could be connected to the distal end of the jaw to control radial motion and another wire connected to the proximal portion of the jaw to control axial motion. The jaw is provided with a straight slot so it can be slid axially into the storage space without transverse motion. These wires may be positioned to extend outside of the tube defining the sample space.

Claims

1. An instrument (10) for obtaining multiple tissue samples (40) from sites within a body (18) without being withdrawn from the body (18), the instrument (10) comprising:

an elongated body (24) having a distal end (16); a storage space (27) defined by the elongated body (24) along the axis of the elongated body (24) near the distal end (16), the storage space (27) suitable for storage of multiple samples (40);

a sampling assembly (20, 21) having a first cutting member (20) and a second cutting member (21), the sampling assembly (20, 21) joined to the elongate body (24) proximate the distal end (16) of the elongated body (24) and being actuatable in a first, radial opening and closing motion to take a tissue sample (40) from the body (18) and a second, axial motion wherein at least one of the first and second cutting members (20, 21) is movable relative to the elongated body (24) so as to pull the sample into the storage space (27).

2. The instrument (10) of claim 1, wherein the sampling assembly (20, 21) is a jaw-like cutting member having a first jaw (20) and a second jaw (21).
3. The instrument (10) of claim 1 or 2, wherein the first cutting member (20) is radially movable and axially stationary, and the second cutting member (21) is radially and axially movable.
4. The instrument (10) of claim 3, wherein the second cutting member (21) is configured to move transversely into space defined by the first cutting mem-

- ber (20) to engage and dispose the sample (40) into the storage space (27).
5. The instrument (10) of claim 1 or 2, wherein both the first and second cutting members (20, 21) are radially and axially movable.
 6. The instrument (10) of claim 1, wherein the sampling assembly (20, 21) is configured to return to a sample cutting position with the sample disposed in the storage space (27) for preparation of taking another sample (40) without being withdrawn from the body (18).
 7. The instrument (10) of claim 1, wherein the second, axial motion is limited between a sample cutting position and a position in the storage space (27) near the distal end (16) for disposing the sample (40) axially into the storage space (27).
 8. The instrument (10) of any one of claims 1 to 7, wherein the sampling assembly (20, 21) is joined to the elongated body (24) via a camming arrangement, whereby the axial motion of at least one of the first and second cutting members (20, 21) relative to the elongated body (24) causes the radial and axial motions of the first and second cutting members (20, 21).
 9. The instrument (10) of claim 8, wherein the camming arrangement includes a slot (28, 60) and a pin (26, 64), wherein one of the slot (28, 60) and the pin (26, 64) is provided on the sampling assembly (20, 21) and the other of the slot (28, 60) and the pin (26, 64) is provided on the elongated body (24).
 10. The instrument (10) of claim 9, further comprising another set of camming arrangement including a second slot (68) on the sample assembly (50) and a third slot (62) on the elongated body (54), the second and third slots (68, 62) configured to engage each other for disposing the sample (40) into the storage space (56).
 11. The instrument (10) of claim 8, wherein the camming arrangement provides opening and closing motions of the first and second cutting members (20, 21) for cutting the sample, axial motion of the at least one of the first and second cutting members (20, 21) for engaging and disposing the sample (40) in the storage space (27), and axial motion of at least one of the first and second cutting members (20, 21) for returning the sampling assembly (20, 21) to the sample cutting position.
 12. The instrument (10) of any one of claim 1 to 11, wherein the sampling assembly (20, 21) is coupled to a distal end portion (16) of the elongated body (24), the distal end portion (16) being rigid relative to the flexible portion of the elongated body (24).
 13. The instrument (10) of claim 12, wherein the rigid distal end portion (16) has an axial length that is approximately equal to or shorter than the axial length of the sampling assembly (20, 21).
 14. The instrument (10) of claim 12, wherein the rigid distal end portion (16) defines a space that has an axial length that is approximately equal to the axial length of the sampling assembly (20, 21) and the sampling assembly (20, 21) is moveable proximally within the distal end portion (16).
 15. The instrument (10) of claim 14, wherein the distal end portion (16) has a length of about 5-7 mm.
 16. The instrument (10) of claim 1, wherein the instrument (10) has a diameter sized to pass through an endoscope.
 17. The instrument (10) of claim 1, wherein the instrument (10) has a length in the range of about 100 - 250 cm.

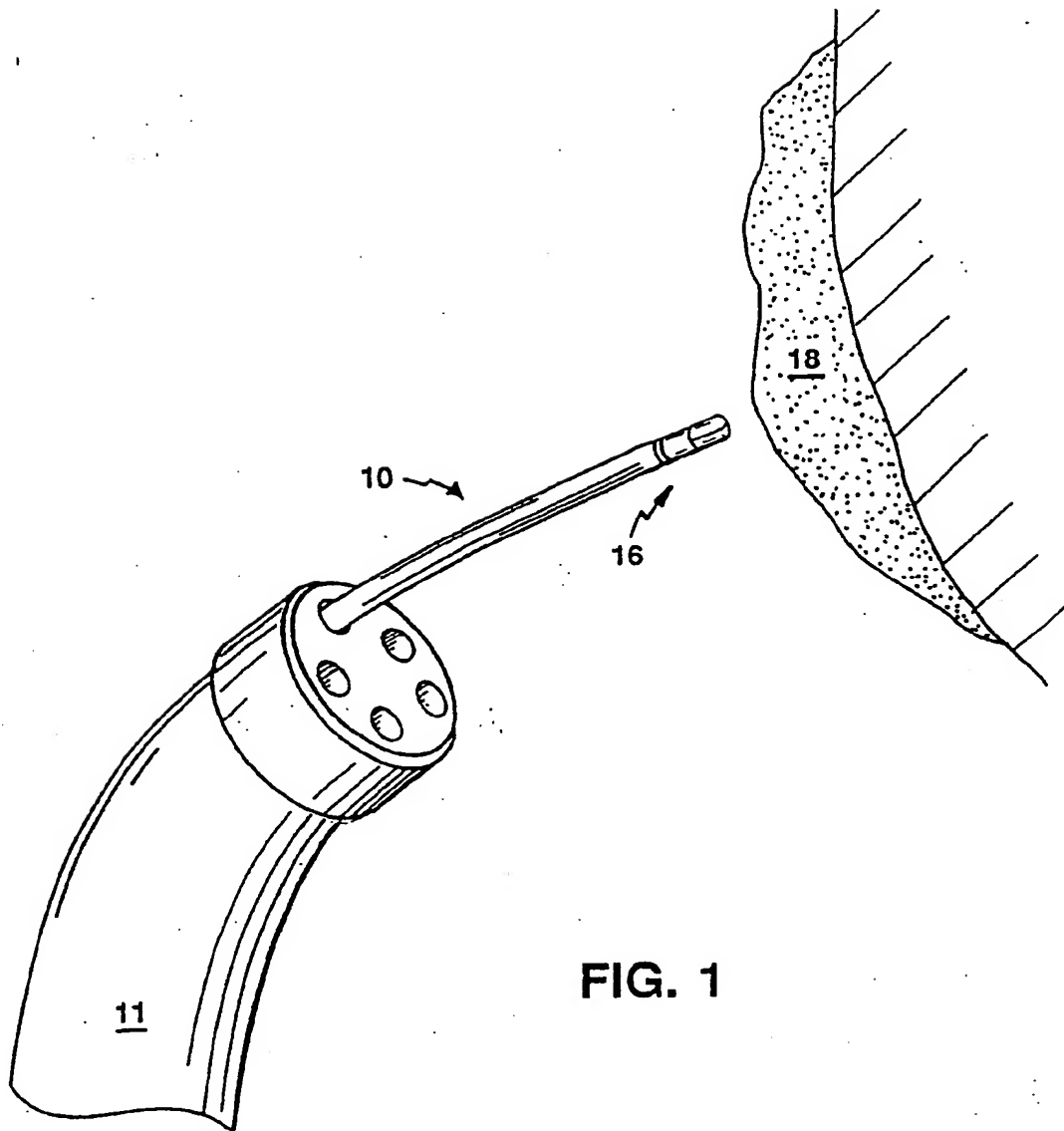


FIG. 1

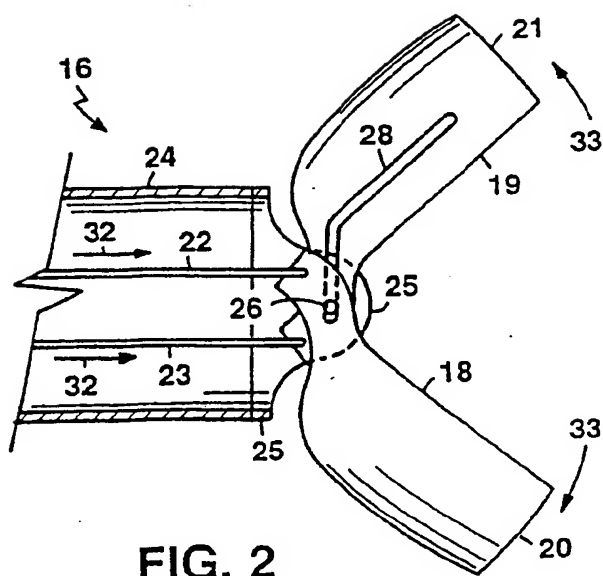


FIG. 2

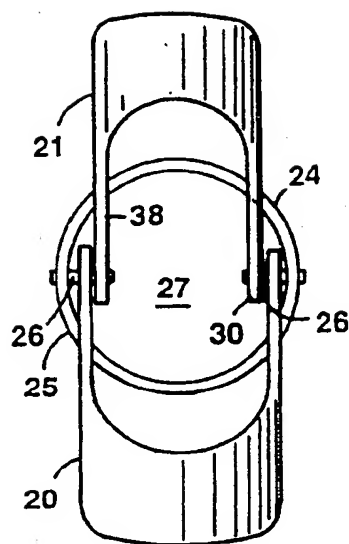


FIG. 2a

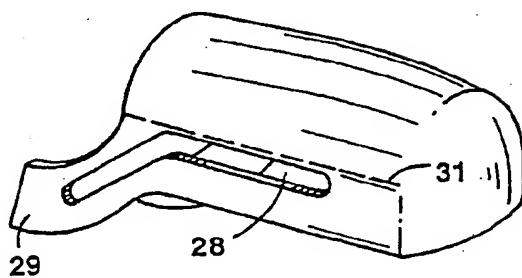


FIG. 2b

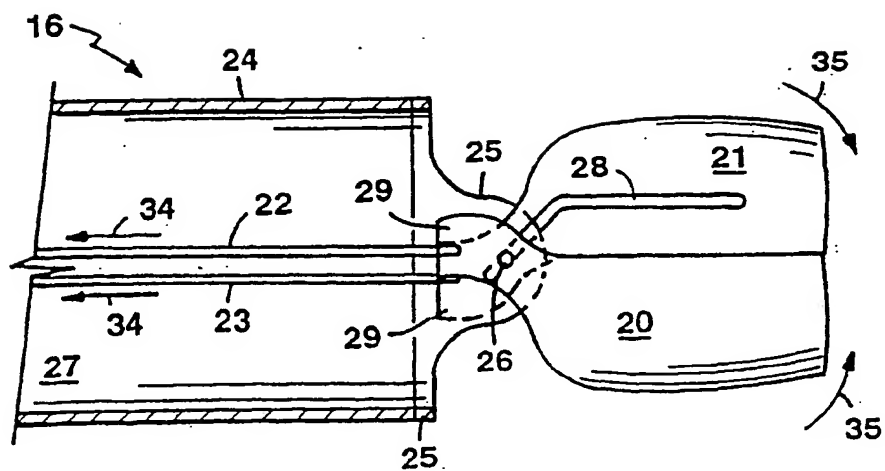


FIG. 3

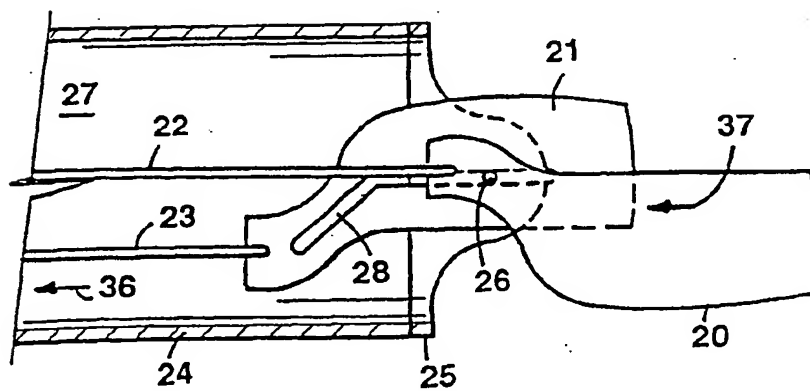


FIG. 4

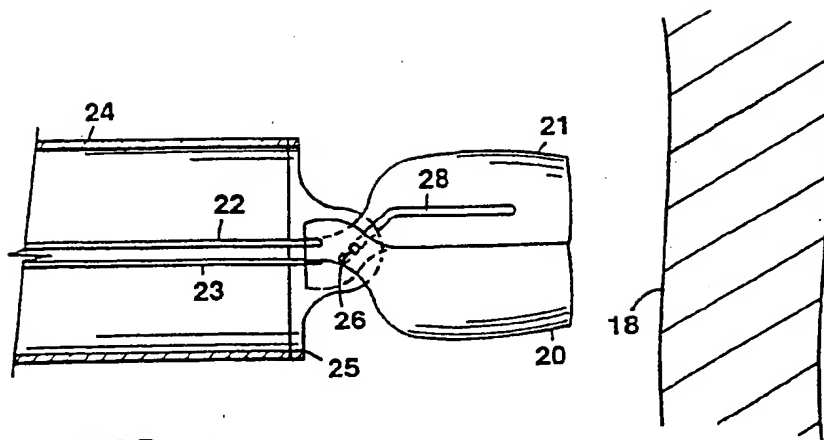


FIG. 5

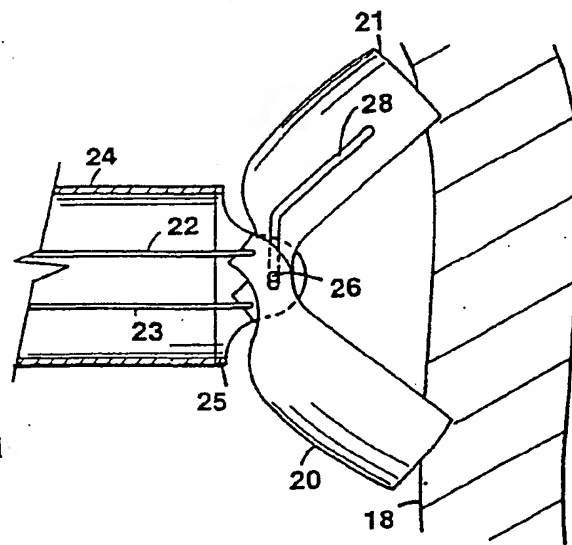


FIG. 5a

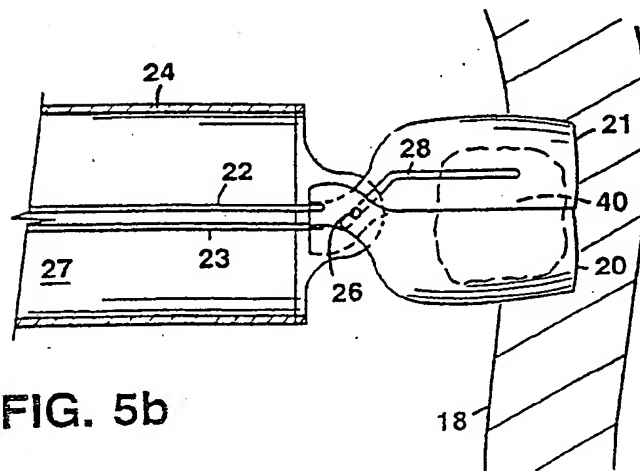
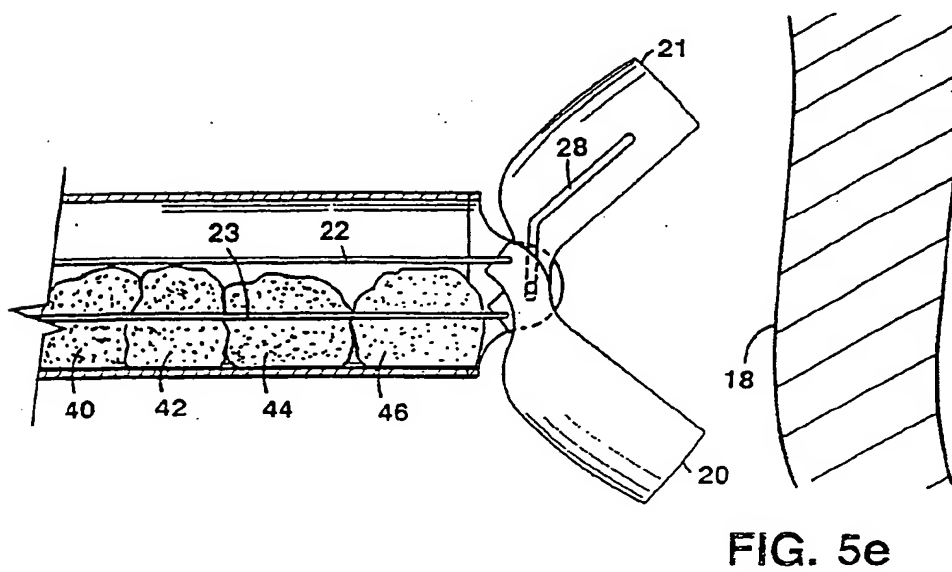
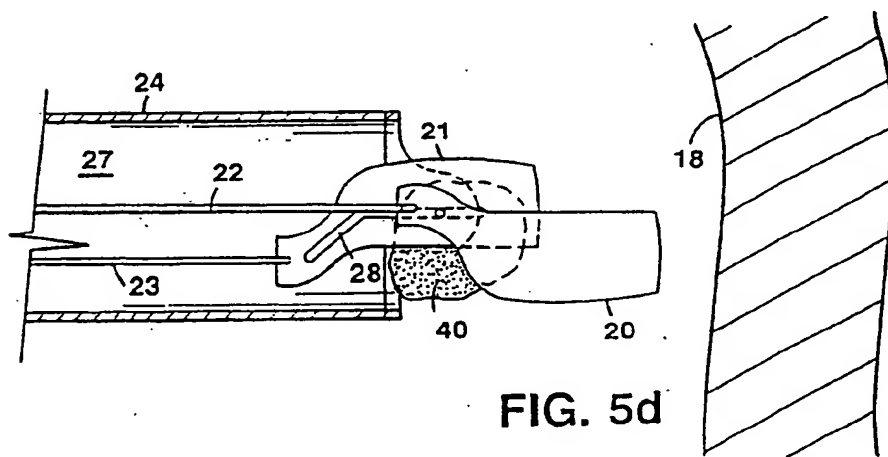
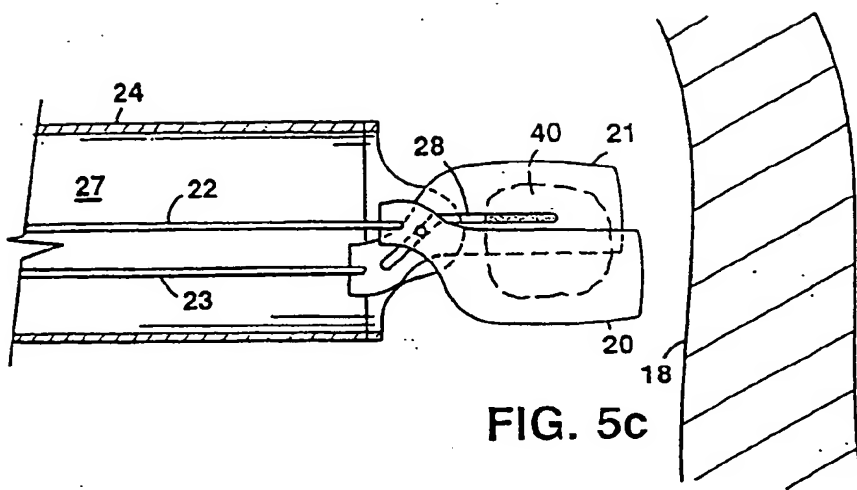


FIG. 5b



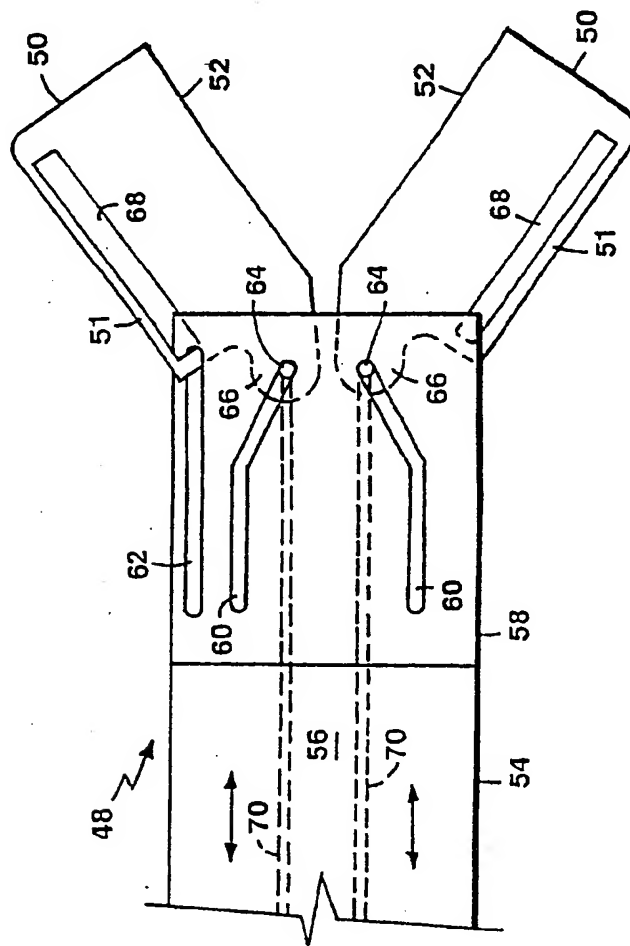
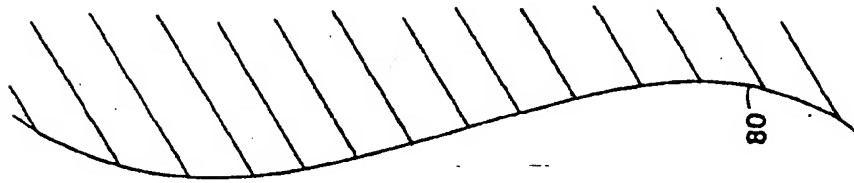


FIG. 6

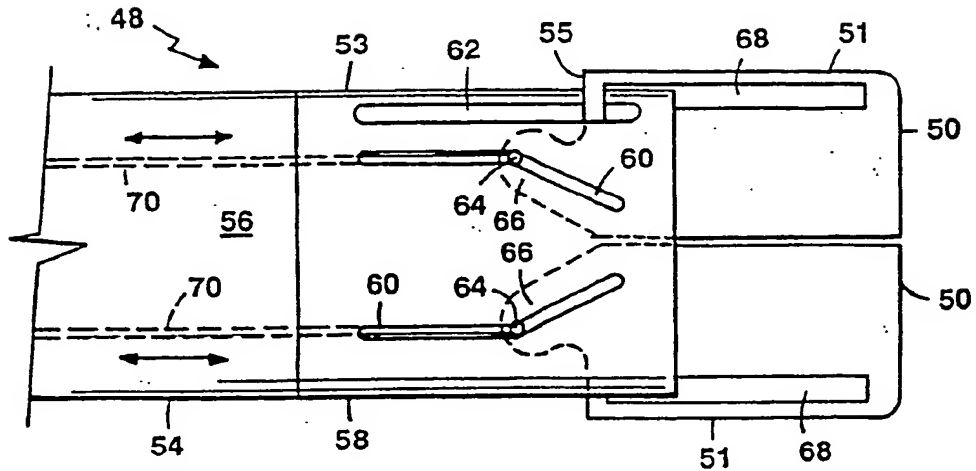


FIG. 6a

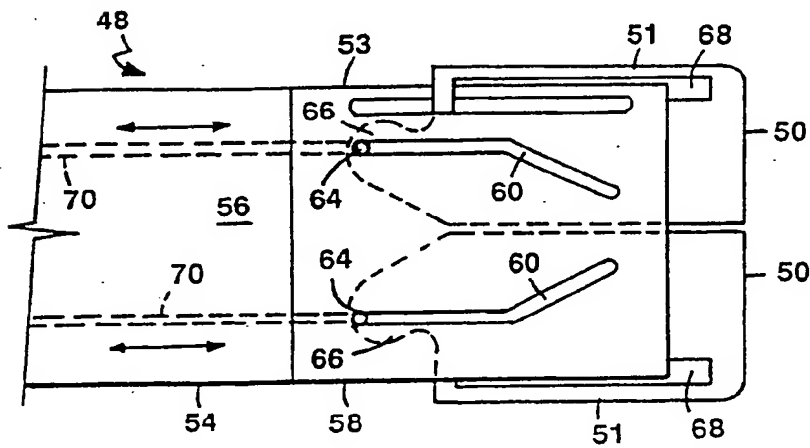


FIG. 6b

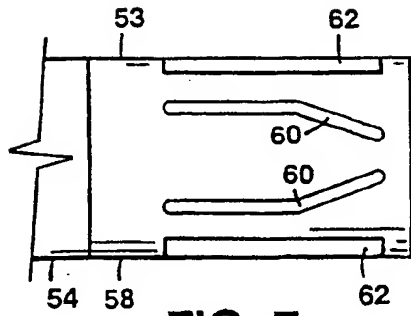


FIG. 7

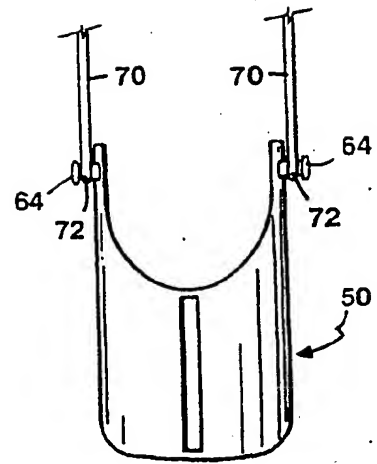


FIG. 7c

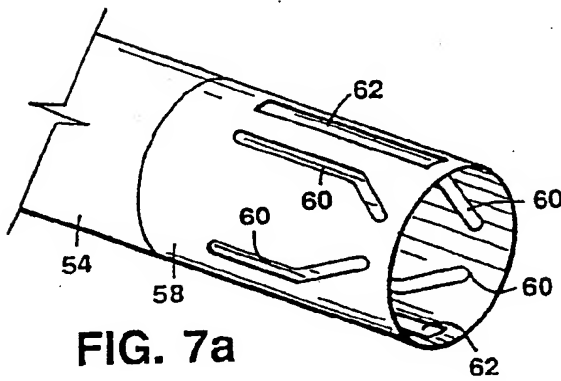


FIG. 7a

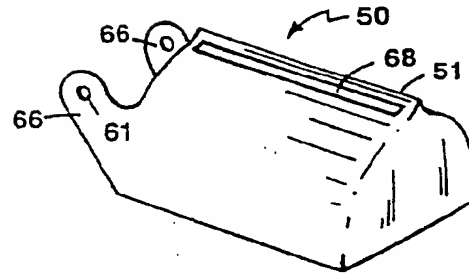


FIG. 7d

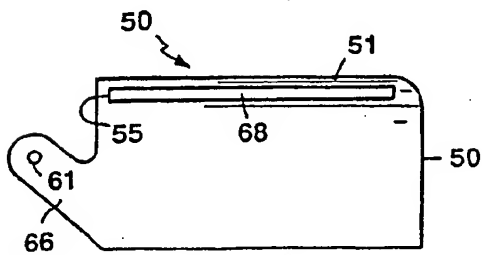


FIG. 7b

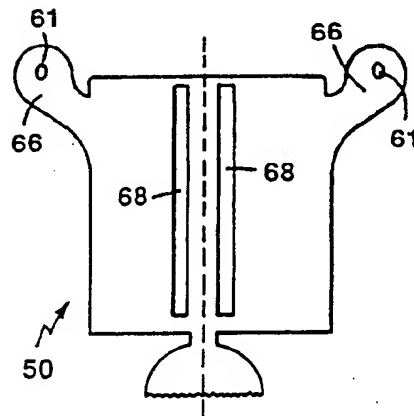


FIG. 7e



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EUROPEAN SEARCH REPORT

Application Number
EP 03 10 1894

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